K090919

Kensey Nash

510(k) Summary

OCT - 2 2009

Submitted by: Kensey Nash Corporation
735 Pennsylvania Drive
Exton, PA 19341

Contact Person: Alyssa J. Schwartz, MS, RAC
Regulatory Affairs Specialist
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Date Prepared: March 30, 2009
510(K) #:
Device:
Trade Name: Kensey Nash Fibrillar Collagen Dental Membrane
Common/Usual Name: Collagen Dental Membrane
Proposed Classification: Barrier, Animal Source, Intraoral
21 CFR 872.3930, NPL, Class II

Device Description:
The Kensey Nash (KN) Fibrillar Collagen Dental Membrane is a translucent, resorbable, non-friable, rectangular collagen membrane sheet derived from bovine tissue. The KN Fibrillar Collagen Dental Membrane is intended for single-use and is sterilized by Ethylene Oxide.

Intended Use:
The Kensey Nash Fibrillar Collagen Dental Membrane is indicated for:

- Simultaneous use of Guided Bone Regeneration (GBR)-membrane and implants.
- Augmentation around implants placed in immediate extraction sites.
- Augmentation around implants placed in delayed extraction sockets.
- Localized ridge augmentation for later implantation.
- Alveolar ridge reconstruction for prosthetic treatment.
- Filling of bone defects after root resection, cystectomy, removal of retained teeth.
- Guided bone regeneration in dehiscence defects.
- Guided tissue regeneration procedures in periodontal defects

Predicate Devices:

Manufacturer	Device	510(k)#
Geistlich Pharma AG	Bio-Gide	K050466
Collagen Matrix, Inc.	Collagen Dental Membrane – Conformable II	K062881

Substantial Equivalence:
Performance Testing has confirmed that the Kensey Nash Fibrillar Collagen Dental Membrane is substantially equivalent to the predicate devices with regard to materials, intended use, and technological characteristics, pursuant to section 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Ms. Alyssa J. Schwartz
Regulatory Affairs Specialist
Kensey Nash Corporation
735 Pennsylvania Drive
Exton, Pennsylvania 19341

OCT - 2 2009

Re: K090919
Trade/Device Name: Kensey Nash Fibrillar Collagen Dental Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: September 25, 2009
Received: September 28, 2009

Dear Ms.Schwartz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number:

Device Name: Kensey Nash Fibrillar Collagen Dental Membrane

Indications For Use:

The Kensey Nash Fibrillar Collagen Dental Membrane is indicated for:

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Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kim Hurley for HSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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